

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Weshington, D.C. 20231

SAPE SAMMER STATION,	SERIAL NUMBER! ' ' 'FILING DATE	FIRST NAMED I	NVENTOR		ATTORNEY DOCKET NO
GRAY E PARKER 18N2/0521 GARY UNIT PAPER NUMBER STANTON, R ART UNIT PAPER NUMBER 3 TANTON, R ART UNIT PAPER NUMBER 7 TANTON, R ART UNIT PAPER NUM	deem freezhalt was tit				
EXAMINER STANTON, It GARY E PARKER 2YMOGENETICS INC 4225 RODSEVELT WAY NE SEATTLE WA 98105 DATE MAILED: 1804 DATE MAILED: 03/21/96 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined and the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined action is set to expire Temperature of the stanton's period for response will cause the application to become abandoned. 35 U.S.C. 133 Perri I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 1.		GARNER	•.	egran -	9315
GRAY E PARKER 2 YM0/GENETICS INC 4225 ROUSEVELT WAY NE 5 EATTLE WA 98105 This is a continuntalization from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined Activated statutory period for response to this action is set to explain from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined Activated statutory period for response to this action is set to explain from the death of this letter. Activate to respond within the period for response to this action is set to explain from the death of this letter. Activate to respond within the period for response to this action is not to explain from the death of this letter. Activate to respond within the period for response to this action is not to explain from the death of this letter. Activate to respond within the period for response to this action is not to explain from the death of this letter. Activate to respond within the period for response to this action. I be death of Activate the period for response to this action is not explain from the death of this letter. Activate to respond within the period for response to this action. I be death of Activate the period for response to this action. Activate the period of Activate the period for response to this action. Activate the period for the death of the action. Be considered or substitute drawlings have been recolved on period for the complete of the death of the dea	AIR SHALL NO. 1 09 109 124	COMPANIETY .			
GRAY E PARKER 2 MODISEVELT WAY NE SEATTLE WA 98105 DATE MAILED: 03/21/96 This application has been examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined and the application of the examiner by the action is made of this letter. Failure to response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 1. Spicio of References Citad by Examiner, PTO-992. 2. Notice of Information on How to Effect Drawing Changes, PTO-1474. 3. Notice of Art Clied by Applicant, PTO-1449. 4. Notice of Information on How to Effect Drawing Changes, PTO-1474. Part II SUMMARY OF ACTION 1. Claims Calms Are withdrawn from considera are withdrawn from considera are allowed. 4. Claims Are pending in the application has been filed with informat drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 5. Claims are allowed. 6. Claims Are proposed additional or substitute sheetig) of drawings, filed on				STANTON,	R 4
GREY E PARKER YMOUGENETICS INC 4225 RODSEVELT WAY NE SEATTLE WA 98105 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined to charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined to charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined to charge of your application. Communication has been examined to charge of your application. Communication has been examined to charge of your application. Communication has been examined to communication filed on Start and days from the date of this letter. Calculate to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMISMITS ARE PART OF THIS ACTION: 1. Statics of Reterences Citad by Examiner, PTO-832. 2. Notice of Direttman's Patent Drawing Review, PTO-152. 3. Notice of Art Cliad by Applicant, PTO-1449. 4. Notice of Informal Patent Application, PTO-152. 5. Information on How to Effect Drawing Changes, PTO-1474. 8. Notice of Informal Patent Application, PTO-152. Of the above, daims are withdrawn from consideration. Claims are withdrawn from consideration. Claims are expected. Claims are expected to restriction or election requirement. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. Claims are objected to restriction or election requirement. Claims are placed trawings have been received on purposes of the claim for protest under 35 U.S.C. 119. The certified copy has Deen received not been noceptable Deen filed in parent application, serial ro. Silver of the claim for pictory under 35 U.S.C. 119. The certified copy has Deen received not been noceptable Deen filed in parent application, serial ro. Silver of the claim for pictory under 35 U.S.C. 119. The certified copy has Deen received not been		18N2/0521		ART LIMIT	PAPER NUMBER
A 225 ROUSEVELT WAY NE SEATTLE WA 98105 DATE MAILED: O3/21/96 This is a communication from the examiner in charge of your application. DOMNISSIONER OF PATENTS AND TRADEMARKS This application has been examined A photoseries statutory period for response to this action is set to expire (mail 1) month(e)					
DATE MAILED: DATE MAILED: DATE MAILED: DATE MAILED: DOS/21/96 This is a communication from the examiner in charge of your application. DATE MAILED: DOS/21/96 This application has been examined					15
DATE MAILED: 03/21/95 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined to this action is set to expire month(s),				1001	
This a a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined FResponsive to communication filed on	SEATTLE WA 98105				
This application has been examined	*			DATE MAILED:	03/21/96
This application has been examined This action is set to expire This action is made	This is a communication from the examiner in cha	arge of your application.			
A shortened statutory period for response to this action is set to expire / month(s),	COMMISSIONER OF PATENTS AND TRADEM/	ARKS			•
A shortened statutory period for response to this action is set to expire / month(s),		ŧ			
A chortened statutory period for response to this action is set to expire / month(s),					
A shortened statutory period for response to this action is set to expire / month(s),	TY	r		lalor	
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 1. Notice of References Cited by Examiner, PTO-892. Notice of Information Drawing Review, PTO Notice of Art Cited by Applicant, PTO-1449. Notice of Information on How to Effect Drawing Changes, PTO-1474. Notice of Imformal Patent Application, PTO-152. Part II SUMMARY OF ACTION 1. Claims	This application has been examined "153	r-Mesponsive to communica	DON THEO ON	,,,,,,	I nis action is made
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 1.	A shortened statutory period for resnance to this.	action is set to expire TAKE	(3) month(s).	-G davs in	om the date of this letter.
Pent I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 1. Notice of References Citad by Examiner, PTO-892. 2. Notice of Art Citsd by Applicant, PTO-1449. 3. Notice of Art Citsd by Applicant, PTO-1449. 4. Notice of Information on How to Effect Drawing Changes, PTO-1474. 8. Notice of Informal Patent Application, PTO-152. 8. Notice of Informal Patent Application, PTO-152. 8. Notice of Informal Patent Application, PTO-152. 9. Ot the above, claims					
1. Notice of References Cited by Examiner, PTO-892. 3. Notice of Art Cited by Applicant, PTO-1449. 5. Information on How to Effect Drawing Changes, PTO-1474. Part II SUMMARY OF ACTION 1. Claims					
3.	Pert I THE FOLLOWING ATTACHMENT(S) A	RE PART OF THIS ACTION	:		
3.	D		• 🗆		
Part II SUMMARY OF ACTION 1. Claims					
Claims			_	ice of Informal Patent	Application, PTO-152.
Claims	5. L. Information on How to Effect Drawing	Changes, PTO-1474	6. LJ		
Claims	PORT IL SURMARIY OF ACTION				•
Citatins					•
Claims	1. Ctaims (-29			ROMOIN	_ are pending in the applica
2. Claims					
are allowed. 4. Ctaims	Of the above, claims			are	withdrawn from considerat
are allowed. 4. Ctaims	2 D Claims				have been cancelled
are rejected. Claims					
are rejected. Claims	3. Ctaims				_ are allowed.
5. Claims					
are subject to restriction or election requirement. 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on	4. Ly Ctaims		STAM	P 4-15	are rejected.
are subject to restriction or election requirement. 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on	5 Claime				are objected to
7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on					_
7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on	6. Ctaims			re subject to restricti	on or election requirement.
8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on					
9. The corrected or substitute drawings have been received on	7. This application has been filed with infor	mal drawings under 37 C.F.F	7. 1.85 which are	acceptable for exam	ination purposes.
9. The corrected or substitute drawings have been received on	a C	on to this Office action			•
are acceptable; and acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on	o roman unawings are required in respons	io io uno Onice SCIOII.			
are acceptable; and acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on					
examiner; disapproved by the examiner (see explanation). 11. The proposed drawing correction, filed					TO-948).
examiner; disapproved by the examiner (see explanation). 11. The proposed drawing correction, filed					
11. The proposed drawing correction, filled has beenapproved; disapproved (see explanation). 12 Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received not been received serial no; filled on 13 Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in	 The proposed additional or substitute sh 			nas (nave) been	□ approved by the
12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no; filed on		iner (see explanation).	: '		
12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no; filed on	examiner; disapproved by the exami				(ann avalanation)
been filed in parent application, sertal no; filed on 13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in		hae	hean Daww		
been filed in parent application, sertal no; filed on 13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in		has	been Dappro	wea; Liasapproved	(See expanauon).
	11. The proposed drawing correction, filed _ 12. Acknowledgement is made of the claim to	for priority under 35 U.S.C. 1	19. The certified	copy has Deen	
	11. The proposed drawing correction, filed _	for priority under 35 U.S.C. 1	19. The certified	copy has Deen	
accordance with the practice under Ex parte Quayre, 1935 C.D. 11; 453 O.G. 213.	11. The proposed drawing correction, filed _ 12. Acknowledgement is made of the claim to been filed in parent application, serial	for priority under 35 U.S.C. 1 no;	19. The certified filed on	d copy has Deen	received not been recei
	11.	tor priority under 35 U.S.C. 1	19. The certified on	d copy has Deen	received not been received.
14. Other	11.	tor priority under 35 U.S.C. 1	19. The certified on	d copy has Deen	received not been received.

Art Unit: 1804

in the second

The amendment filed 5/12/95 (Paper No. 10) and the declarations submitted under 37 C.F.R. § 1.132 executed by Gerald W. Lasser and Donna E. Prunkard (the Lasser and Prunkard declarations, respectively) have been entered. These declarations have been considered as indicated hereinbelow.

Claims 1-29 remain pending in the instant Application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The outstanding objection to the specification wherein it was indicated that the specification fails to provide an enabling disclosure for any embodiments of what is claimed is hereby withdrawn. However, it is maintained that the specification fails to provide an enabling disclosure for the full scope of what is claimed. Therefore, the outstanding grounds of objection to the specification and corresponding rejection of the claims under 35 U.S.C. § 112, first paragraph, has been restated as indicated hereinbelow. This is the same grounds of objection/rejection as advanced in the preceding Office Action mailed 2/6/95 (Paper No. 9).

Claims 2, 12, and 17 stand rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to mammals and those species of mammals that have been specifically enabled by the prior art for the preparation of transgenic animals that express transgene constructs in their milk. See M.P.E.P. §§ 706.03(n) and 706.03(z). Applicant's arguments filed 5/12/95 (Paper No. 10) have been fully considered but they are not deemed to be persuasive regarding this restated grounds of rejection.

It is maintained that the specification fails to provide an enabling disclosure for the preparation of any and all transgenic animals because the teachings present in the specification are limited to guidance in regard to how one would have transgenic mice and sheep and the artisan would have been required to have exercised undue experimentation in the preparation and use of animals that were not enabled either by the prior art or by teachings present in the instant specification. Thus, generic claims drawn to mammals, while encompassing inoperative embodiments are not precluded from issue. However, claims to and reciting particular embodiments of the invention that would not have been considered to have been enabled by those skilled in the art fail to comply with the requirements of 35

Art Unit: 1804

U.S.C. § 112, first paragraph. In this regard, it is noted that claims 2, 12, and 17 recite methods that required transgenic cattle. However, the state of the art at the time of the claimed invention and ensuing after the time of the invention indicate that the artisan would not have accepted, a priori, that one could have produced fibrinogen in transgenic cattle as required by the instantly pending claims. For example, a 1994 reference by Houdebine (Y) indicates that transgene expression in milk had not been observed in cattle (see e.g. Tables 4-6) and that regulatory sequences must be tested empirically, leading to unpredictable success and failure (page 274, paragraph bridging columns 1 and 2). Even post-filing, the artisan was unable to predictably use transgenic cattle. For example, a 1996 manuscript by Wall (X) states on page 62, first paragraph that "...transgene expression and the physiological consequences of transgene products in livestock are not always accurately predicted in transgenic mouse studies". Wall further states on page 62, third paragraph, lines 8-10, that "(c)urrently, the only approach that yields truly informative data is testing transgenes in livestock of interest". Thus, based upon the unpredictable nature of the transgene expression art and the particular inoperability in the production of transgenic cattle, it is maintained that the artisan would not have been able to have practiced the methods as required for the inventions as claimed by claims 2, 12, and 17 without having had to have exercised undue experimentation.

Applicant argues that they have provided a variety of examples and teachings that would have enabled the artisan to have practiced the full scope of what is claimed and that those embodiments that are not specifically enabled by the as-filed specification would have been enabled by the prior art as interpreted by the skilled artisan. However, given the nature of what is claimed and the difficulties in preparing transgenic cattle, it is maintained that the preparation of the transgenic cattle required for the practice of the claimed invention would have required undue experimentation.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Art Unit: 1804

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-8 and 11-29 stand rejected under 35 U.S.C. § 103 as being unpatentable over Meade et al., 1989 (A), Archibald et al., 1990 (A4), and Roy et al., 1991 (A7) for reasons of record advanced in the preceding Office Action mailed 2/6/95 (Paper No. 9). Applicant's arguments filed 5/12/95 (Paper No. 10) have been fully considered but they are not deemed to be persuasive.

Applicant argues that they have been able to have prepared biocompetent fibrinogen and that such production would have been expected. In response, it is noted that the as-pending claims do not recite the preparation of such biocompetent fibrinogen and based on the use of animals as bioreactors and in the absence of any requirement for any particular functionality of recited fibrinogen, it is maintained that the claimed invention would have been *prima facie* obvious.

Applicant has submitted declarations under 37 C.F.R. 1.132 executed by Gerald W. Lasser and Donna E. Plunkard. These declarations evidence the production of biocompetent fibrinogen in transgenic mice. However, as the claims do not recite the nature of the fibrinogen produced in the transgenic animals, these declarations fail to support any unexpected results that are concordant with the as-claimed invention.

Applicant is advised that revision of the claims to recite the production of "biocompetent" fibrinogen would overcome the outstanding grounds of rejection under 35 U.S.C. § 103.

Claims 9 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Meade et al., 1989 (A), Archibald et al., 1990 (A4), and Roy et al., 1991 (A7) as applied to claims 1-8 and 11-29 above, and further in view of Chung et al., 1990 (A18) and Lewin, 1983 (R) for reasons of record advanced in the preceding Office Action mailed 2/6/95 (Paper No. 9). Applicant's arguments filed 5/12/95 (Paper No. 10) have been fully considered but they are not deemed to be persuasive.

Applicant's arguments have been fully addressed above in the rebuttal of the arguments advanced against the preceding grounds of rejection under 35 U.S.C. § 103.

No claims are allowable.

Art Unit: 1804

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Stanton whose telephone number is (703) 308-2801. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone can be reached on (703) 308-3153. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1096.

Brian R. Stanton, Ph.D. 21 May 1996

BRIAN R. STANTON PATENT EXAMINER GROUP 1800

Buch Stanton